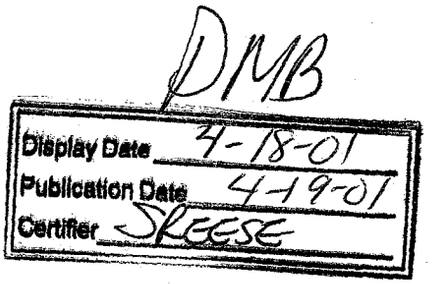

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0785]

Guidance on Medical Device Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Guidance on Medical Device Patient Labeling." This guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Guidance on Medical Device Patient Labeling" to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important to help assure the safe and effective use of devices. This guidance document was published for public comment on March 3, 2000, as a draft proposal entitled "Guidance on Medical Device Patient Labeling."

Both the draft guidance document and the March 2000 notice provided an opportunity for public comment, which closed June 2, 2000. Based on the comments received, the following substantive changes have been incorporated into the final version of the guidance.

1. FDA inserted a paragraph in "What is the purpose of this guidance?" explaining that when translating the professional label into lay language, care should be taken to ensure that the lay language does not alter the intent of the indications, contraindications, warnings and precautions, or other parts of the labeling.

2. The sections "When should you use medical device patient labeling?" and "Determining Sequence and Content" were restructured and revised for clarity. Both sections were clarified to focus on the needs of the specific target population for the device rather than an inflexible formula.

3. The section entitled "Alternatives to the device and treatment" was deleted.

4. Changes were made to address the safe and proper methods of disposing of medical devices.

5. FDA has clarified that clinical studies information can be provided either as part of the patient labeling, or upon request.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device patient labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted the good guidance practices (GGP's) regulation, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Guidance on Medical Device Patient Labeling" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2 and then enter the document number (1128) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "Guidance on Medical Device Patient Labeling," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

"Guidance on Medical Device Patient Labeling" will be available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the guidance at any time. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/2/01

April 2, 2001

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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